Traditional 510(k) Summary

K093280

Date of Preparation: 20 December 2010

JAN - 7 2011

1) Applicant Name & Address

OPTI Medical Systems, Inc.
235 Hembree Park Drive
Roswell, GA 30076

2) Purpose for Submission:

Addition of Lactic Acid (lactate) test (Class I) to cleared OPTI CCA-TS analyzer system
Modify pH, PO_2, and PCO_2 sensors to dry-stored type on cleared OPTI CCA-TS analyzer system

3) Applicant Contact

Primary Contact Person
Len Owens
VP Quality and Regulatory Affairs
Email: len.owens@optimedical.com
Office: (770) 688-1658
Fax: (770) 510-4445

Secondary Contact Person
Paul Travers
Director Research and Development
Email: Paul.Travers@optimedical.com
Office: (770) 688-1682
Fax: (770) 510-4445

4) Establishment Registration Number

The establishment registration number is: 3004102403

5) User Fee Payment ID: MD6045790-956733

6) Device Trade/Proprietary Name

B-Lac cassette for OPTI CCA-TS Critical Care Analyzer system

7) Device Common Name

Blood analysis system - gases, pH, Lactic Acid, Hemoglobin, and Oxygen saturation

8) Device Classification

Product Nomenclature	Regulation	Product Code	Class	Panel
ACID, LACTIC, ENZYMATIC METHOD	862.1450	KHP	I	CHEMISTRY (75)
ELECTRODE, BLOOD GASES (PCO_2, PO_2) AND BLOOD PH	862.1120	CHL	II	CHEMISTRY (75)
SYSTEM, HEMOGLOBIN, AUTOMATED	864.5620	GKR	II	HEMATOLOGY (81)
OXIMETER, WHOLE BLOOD	864.7500	GLY	II	HEMATOLOGY (81)

9) Description of Device

The OPTI CCA-TS system is a portable [4.7 x 14.2 x 9.1 inches, 12 pounds], microprocessor-based instrument using optical fluorescence for the measurement blood gases, electrolytes and enzymes and utilizes a graphical touch screen interface. There is an additional laser based measurement of total hemoglobin (tHb) and SO_2 capability available with any cassette that contains a pO_2 sensor.

The OPTI CCA-TS system is currently cleared [K993837, K984299, and K974784] for the measurement of pH, PO_2, PCO_2, Na, K, Ca, Cl, Glucose, BUN (Urea), tHb and SO_2. Measurements made on the OPTI CCA-TS system require the use of the OPTI CCA-TS analyzer, a disposable cassette containing fluorescent sensors for the measurement of the analytes (except tHb and SO2) and presentation of the blood sample for measurement of tHb and SO_2 by lasers on board the CCA-TS analyzer, and software to calculate measurements from the optical data provided by the analyzer for a blood sample and perform on-board QC tests to safeguard results using known standards.

OPTI Medical has designed a lactic acid (lactate) sensor to provide lactate results when a cassette containing the lactate sensor is used with the OPTI CCA-TS analyzer. The B-Lac cassette is a disposable, single use cassette that contains four (4) sensors for *in vitro* measurements of pH, PCO_2, PO_2, and Lactate. The B-Lac cassette is sealed in a foil pouch along with a desiccant and is marked with a barcode label that includes a lot identification number, calibration information, and expiration date.

The OPTI Critical Care Analyzer (CCA-TS model) hardware is unchanged from the design described in the most recent clearance [K993837] of the device. The capacity to add analytes was part of the design since product inception and electromagnetic compatibility is unaffected. Software changes were made to add the lactate measurement algorithms and operational features for the B-Lac cassette addition.

10) Intended Use / Indications for Use

The OPTI CCA-TS B-Lac cassette is intended to be used for in vitro measurements of pH, PCO_2, PO_2, lactate (lactic acid), total hemoglobin (tHb), and oxygen saturation (SO_2), in heparinized whole blood samples (either arterial or venous) on the OPTI CCA-TS system, in either a clinical setting or point-of-care locations.

Measurements of blood gases (PCO_2, PO_2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances. Lactate (lactic acid) measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood). Total hemoglobin measurement is used to determine the hemoglobin content of human blood. Oxygen saturation measurement is used to determine the oxygen capacity of the hemoglobin.

The OPTI CCA-TS B-Lac cassette is for prescription use only.

11) Substantial Equivalence

The CCA-TS B-Lac cassette is substantially equivalent in safety, function, and efficacy to several currently marketed devices already on the market known as 'Combi Analyzers' and 'Point of Care' analyzers. Specifically, the sensors in the B-Lac cassette are shown to be equivalent to the Instrument Laboratory Co. GEM Premier 4000 [K061974] for the measurement of blood gases and ph, total hemoglobin, oxygen saturation, and lactic acid. Non-clinical studies were performed to demonstrate equivalence when compared to the predicate device and to gravimetric tonometry standards for the Blood Gases (PO_2, PCO_2). Clinical site studies demonstrated substantial equivalence when compared to legally marketed devices in a clinical setting at multiple sites by several personnel trained to perform and report these analyses. Specimens analyzed were remnant from patient samples of whole blood collected from routine

analysis on existing instrumentation. Samples were aspirated into the OPTI CCA-TS B-Lac cassette from both heparinized syringes and heparinized capillary tubes.

12) Identification of Predicate Device

Manufacturer	Device Name	510k Number
Instrument Laboratory Co. (IL)	GEM Premier 4000	K061974

13) Comparison with Predicate Device

OPTI CCA-TS B-Lac cassette is the device being introduced to enable the OPTI CCA-TS system to report lactate measurements and report pH, PO_2, and PCO_2 measurements using modified dry sensors. This table shows how the device compares to the predicate device:

	OPTI CCA – TS B-Lactate Cassette	GEM Premier 4000	Comparison
510(k) #	To be determined	K061974	
Item	Device	Predicate	
Intended use	The OPTI CCA-TS B-Lac cassette is intended to be used for in vitro measurements of pH, pO_2, pCO_2, lactate (lactic acid), total hemoglobin (tHb), and oxygen saturation (SO_2), in heparinized whole blood samples (either arterial or venous) on the OPTI CCA-TS system, in either a clinical setting or point-of-care locations.	The GEM Premier 4000 is a portable system for use by health care professionals to rapidly analyze whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory. The instrument provides quantitative measurements of pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glucose, Lactate hematocrit, and CO-Oximetry (tHb, O2Hb, COHb, MetHb, HHb) parameters.	Similar
Where use	Hospital	Hospital	Same
Measured Parameter	Lactate, pH, PCO_2, PO_2, tHb and SO_2	Lactate, pH, pCO_2, pO_2, Na, K, Ca, Cl, Glu, Hct, tHb, O_2Hb, COHb, MetHb, HHb, Total Bilirubin	Similar
Calculated Parameters	BE, ctO_2, HCO_3-, PCO_2^t, BEact, BB, st HCO_3-, BEecf, cH+, Hct(c), st.pH, P50, SO_2(c)	TCO2, P/F Ratio, BE(B), pAO2, BE(ecf), CaO2, tHb(c), CvO2, Ca++ (7.4), p50, Anion gap O2cap, sO2, RI, sO2(c), CcO2, HCO3-std, a-vDO2, HCO3-(c), Qsp/Qt (est), A-aDO2, Qsp/Qt, paO2/pAO2, Hct(c)	Similar
Sample Type	Whole blood (heparinized, venous or arterial)	Whole blood samples	Same
Reportable ranges	pH: 6.6 to 7.8 *P*O2: 10-700 mmHg *P*CO2: 10-200 mmHg Lactate: 0.3 to 17.5 mmol/l tHb: 5.0 – 25 g/dL	pH: 6.8 to 8.0 *P*O2: 0-800 mmHg *P*CO2: 0-150 mmHg Lactate: 0.1 to 20.0 mmol/l tHb: 5.0 – 23.0 g/dL	Similar
Sample	125 µL	65 -150 µL	Similar

	OPTI CCA – TS B-Lactate Cassette	GEM Premier 4000	
Volume			
Test consumable	One use cassette with optical fluorescence multi-sensor array Port for sample introduction Fluid waste chamber	One use cartridge with Electrochemical multi-sensor array Port for sample introduction Fluid waste chamber	Similar
Test consumable storage	Refrigerated storage until expiry date including max 14 days at room temperature.	15-25^{0}C until expiry date	Similar
Measurement sequence	Calibrate cassette - introduce sample - measure	Calibrate test cartridge – introduce sample - measure	Similar
Measurement time	180 sec from sample introduction	70-95 sec	Similar
Measurement Temperature	37^{0}C	37^{0}C	Same
Error detection	QC system to detect user errors QC system for reader self check QC system to detect cassette non-conformance	QC system to detect user errors QC system for reader self check QC system to detect test cartridge non-conformance	Similar
Measurement Principle	pH: fluorescence *P*O2: fluorescence *P*CO2: fluorescence Lactic acid – Lactate oxidase based fluorescent oxygen detection tHb and SO2 – Optical reflectance measurement.	pH: electrochemical *P*O2: electrochemical *P*CO2: electrochemical Lactic acid – Lactate oxidase based amperometric peroxide detection Hematocrit and CO-Oximetry – Optical measurement of hemoglobin and fractional derivatives of hemoglobin in lysed blood	Similar

14) Technological Characteristics

Principle of Measurement

The single use B-Lac cassette contains a port that allows the introduction of a sample to an array of sensors sealed inside the cassette. The OPTI CCA-TS analyzer aspirates the sample from a capillary tube or syringe. The sensors use fluorescence optodes to measure the intensity of light emitted from fluorescent dyes exposed to specific analytes. The concentration of the analyte is determined by the calculation of the difference in fluorescence measured at a defined calibration point and that measured with the unknown concentration of analyte. The principles of measurement of pO2, pCO2 and pH for the B-Lac cassette are similar to those used with existing cassette styles that are used on the OPTI CCA platform [K993837, K984299, and K974784].

The lactate measurement is based on the enzymatic oxidation of lactate.

$$\text{L-Lactate} + O_2 \xrightarrow[\text{Lactate Oxidase}]{} \text{Pyruvate} + H_2O_2$$

The sensor is constructed of an enzyme layer over an oxygen sensor. As a sample containing lactate contacts the sensor this enzymatic oxidation of the lactate consumes the oxygen locally

present in the sensor. This decrease in oxygen is detected by the oxygen sensor. The amount of lactate is determined to be proportional to the rate at which the oxygen is consumed.

15) Summary of Non-Clinical Testing

Electrical Standards:
The cleared OPTI CCA-TS analyzer system [K993837, K984299, K974784] has been tested and found to comply with EN61010-1 Safety Requirements for Electrical Equipment, FCC Class A Radiated and Conducted Emissions, EN55022 Radiated and Conducted Emissions, EN61000-3-2 Quasi-Stationary Current Harmonics, EN61000-3-3 Voltage Fluctuation and Flicker Test, and EN61326-1 Electrical Equipment Electromagnetic Compatibility standards. No changes were made to the cleared analyzer system to add the B-Lac cassette so the studies cited above remain valid.

Performance:
In-house studies were conducted using CLSI guidelines on both aqueous controls and whole blood samples to demonstrate acceptable precision, accuracy, reproducibility, and linearity across the claimed measurement ranges with both syringe and capillary tube sampling methods. Limit of detection and interference studies were completed using CLSI standard methods and are summarized in device labeling.

The OPTI CCA-TS system is calibrated with methods traceable to NIST standards.

Stability studies were performed on the B-Lac cassette design and Instructions for use are included with the B-Lac cassette style to instruct the user of the storage and use limitations.

CCA-TS software required modification to add the lactate sensor calculations and modify the calculation parameters in algorithms for the dry storage pH, *P*CO2, and *P*O2 sensors used in the B-Lac cassette. The CCA-TS software level of concern is moderate based on an assessment of the software in its intended use using tables 1 and 2 in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005. Software modifications were made, verified, and validated as outlined in the guidance document cited above.

16) Summary of Clinical Site Testing

Precision and accuracy of the OPTI CCA-TS system with the B-Lac cassette was verified at multiple user sites and data provided in the 510(k) demonstrates performance equivalent to marketed devices used for method comparisons. Whole blood sample discards were used by multiple clinicians and introduced to the analyzer system in both heparinized syringes and heparinized capillary tubes to demonstrate equivalence between the two sampling modes and to marketed reference analyzers.

17) Conclusion

Analysis of the method comparison data collected during clinical site studies for this device presented in this 510(k), together with the linearity and precision data collected during non-clinical and clinical studies demonstrates that the OPTI CCA-TS system with B-Lac cassette is safe, effective, and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JAN 0 7 2011

OPTI Medical Systems, Inc.
c/o Mr. Len Owens
Vice President of Quality & Regulatory Affairs
235 Hembree Park Drive
Roswell, Georgia 30076

Re: k093280
Trade Name: OPTI CCA-TS B-Lac cassette
Regulation Number: 21 CFR §862.1120
Regulation Name: Blood gases (PCO_2, PO_2) and blood pH test system.
Regulatory Class: Class II
Product Codes: CHL, KHP, GKR, GLY
Dated: December 21, 2010
Received: December 27, 2010

Dear Mr. Owens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K093280

Device Name: OPTI CCA-TS B-Lac Cassette

JAN - 7 2011

Indications for Use:

The OPTI CCA-TS B-Lac cassette is intended to be used for in vitro measurements of pH, PCO_2, PO_2, lactate (lactic acid), total hemoglobin (tHb), and oxygen saturation (SO_2), in heparinized whole blood samples (either arterial or venous) on the OPTI CCA-TS system, in either a clinical setting or point-of-care locations.

Measurements of blood gases (PCO_2, PO_2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances. Lactate (lactic acid) measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood). Total hemoglobin measurement is used to determine the hemoglobin content of human blood. Oxygen saturation measurement is used to determine the oxygen capacity of the hemoglobin.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093280